

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.

Petitioners,

v.

THE FOUNDRY, LLC,
Patent Owner.

Case No. IPR2024-00280

U.S. Patent No. 10,894,011

PETITIONERS' REPLY

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I. INTRODUCTION

The Challenged Claims are unpatentable, and Patent Owner's ("PO") legally irrelevant and technically incorrect arguments do not show otherwise.

The Board correctly found no relevant priority application provides written description for the challenged energy-only treatment claims. Institution Decision ("ID"), 22-26. With the specification describing energy facilitating *toxin* therapy *not* energy-only therapy, PO merely argues the claimed treatment was *obvious* based on passing reference to non-reversible poration. Obviousness, however, is insufficient for written description. Absent earlier priority, Grounds I-II are *uncontested* and render all Challenged Claims unpatentable.

Regardless, Ground IV renders all Challenged Claims obvious. For claim 1, PO's suggestions that a POSITA would not even consider parts of indisputably analogous art are improper. So too is its mischaracterization of Makower as inoperable based on a scenario Dr. Levine testified *was not an issue*. As Dr. Bu-Saba explains, a POSITA would have expected Makower's device would be safe and effective, as it teaches. And far from being inconclusive, Fang concludes, from statistically significant data, that radiofrequency ablation treated rhinitis symptoms. None of PO's arguments overcome the prior-art motivation to use Makower's radiofrequency electrode device to reasonably expect known benefits Fang (and

others) taught. PO's arguments regarding dependent claim 9—which are inconsistent with the '011 patent—fare no better.

Facing preponderant obviousness, PO resorts to disparaging Petitioners' eminently qualified expert despite raising *no disputed issue* he is unqualified for. Most issues are, in fact, undisputed, and where the declarants disagree, the evidence supports Petitioners.

II. GROUNDS I-III: THE PRIORITY DATE IS NO EARLIER THAN OCTOBER 22, 2019

The only priority dispute is whether the '771 Provisional (incorporated in the '090 Application) provides priority before October 22, 2019. It does not, because it does not provide written description for the claims. Pet., 19-27; ID, 15-18. PO's argument that energy-only treatment would have been obvious is not enough to show otherwise, and its reliance on nested incorporation of a provisional is also legally improper. The Board should maintain that the claims are entitled to priority no earlier than October 22, 2019. ID, 18. Should it do so, Grounds I and II are uncontested.¹

¹ If the Board finds written description but no legal priority claim, Ground III is uncontested. Pet., 54-64.

A. The Challenged Claims Do Not Have Written Description Support

The Challenged Claims do not have written description support in any earlier application. For priority, PO must show written description in an earlier application that “reasonably conveys to [POSITAs] the inventor had possession of the claimed subject matter.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). Disclosure “that merely renders the invention obvious” is insufficient. *Id.*, 1352 (citation omitted).

The Challenged Claims recite energy-only treatment. Ex.1001-USP011, claim 1; POR, 24-25. RPI Aerin—the patent’s exclusive licensee—correctly represented to the Office “the *sole* purpose of applying energy” the ’771 Provisional describes is *not* treatment but “porat[ing] target cells to enhance uptake of a nerve toxin.” Ex.1034-FH221-Aerin, 786; Pet., 26-27.² PO does not address this binding admission.³ Instead, PO argues claims to energy-only treatment find written description in a *single* parenthetical reference to “non-reversible” poration and

² All emphasis and annotations added.

³ PO also ignores Applicant separately pursued treating nasal conditions *without* neurotoxins. Pet., 24, n.12.

unconnected discussion of mucus cells and areas of administration. POR, 27-31.

These arguments fail.⁴

First, PO wrongly suggests, POR, 23, that the specification describes energy-only treatment.⁵ PO's claim that "[t]he '011 patent relates to an apparatus 'for altering autonomic nerve function by utilizing an electric field...." POR, 23 (quoting Ex.1001-USP011, 4:55-56), is incorrect. The (omitted) end of this specification sentence explains energy is used "to alter tissue...*via permeabilization...to facilitate the translocation of* toxin. Ex.1001-USP011, 4:54-60. The '011 patent discloses toxin, not energy alone, treats rhinitis symptoms. Pet., 26-27; Ex.1001-USP011, Title, Abstract, 1:35-44 ("present invention" delivering "therapeutically effective amount of...neurotoxin"); 3:27-58 ("improved methods...*for delivering toxins*"); 5:15-18; 8:40-62; 21:43-22:3. The Board correctly confirmed this at institution. ID, 15-18. Ex.1098-Reply-Decl., ¶¶50-55.

⁴ Petitioners do not concede unchallenged claims 15 and 19-20 have written description. POR, 25.

⁵ Without conceding earlier priority, Petitioners adopt the Board's shorthand of referencing the '011 patent. See ID, 14-18.

Second, PO cannot rely on a single reference to “non-reversible” poration, POR 27 (citing Ex.1001-USP011, 8:6-13), for written description of treatment because the specification does not describe non-reversible poration **alone** treats rhinitis symptoms. PO does not actually dispute this, but instead argues a POSITA “would recognize” or “would have appreciated” what is claimed. POR, 27, 30; Ex.1089-Levine-Tr., 186:3-7. This is insufficient; what a POSITA “would have” recognized or appreciated relates to **obviousness**, which cannot substitute for written description. *Ariad*, 598 F.3d at 1351; *Impact Engine, Inc. v. Google LLC*, 2024 WL 3287126, at *10 (Fed. Cir. July 3, 2024) (testimony POSITA “would have understood” element insufficient); *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1164-65 (Fed. Cir. 2019) (written description of treatment limitation required description of why treatment effective); *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (no written description if POSITA must “speculate as to [undisclosed] modifications”).

Regardless, PO is wrong about how a POSITA would have understood the '011 patent.⁶ The specification sentence referencing non-reversible poration is directed to “enhanc[ing] delivery” of toxin. Ex.1001-USP011, 8:6-13. A POSITA would have understood the specification refers to non-reversible poration as a potential *undesirable* side effect of reversible poration (in some instances). See Ex.1091-Bikson-Tr., 57:10-19. This is different from disclosing destroying target cells in sufficient numbers for treatment. Ex.1098-Reply-Decl., ¶¶56-61.

Nor does description of mucus-secreting cells, POR, 29-30, describe destroying such cells with non-reversible poration alone for treatment. The specification describes effects *of toxin*, not irreversible poration, on such cells. *E.g.*, Ex.1001-USP011, 1:62-2:18, 3:27-51. PO’s declarant, Dr. Levine, admitted the specification contains no non-reversible poration data and was aware of no prior art use of irreversible electroporation alone for therapy. Ex.1089-Levine-Tr, 186:3-7, 197:1-6. And Dr. Bikson confirmed use of irreversible poration depends on multiple factors. Ex.1091-Bikson-Tr., 55:9--57:9, 59:1-60:2, 60:7-13, 65:10-67:8. PO’s

⁶ PO incorrectly equates non-reversible poration and ablation, POR, 27-29, treatment with which is not the same. Dr. Bu-Saba did not testify otherwise. POR 27-28; Pet. 11-13, 26-27. Ex.1098-Reply-Decl., ¶59.

suggestion a POSITA “would have appreciated” the named inventors possessed the claims based on referencing non-reversible poration with unstated, unknown, and contingent effects should be rejected. Ex.1098-Reply-Decl., ¶62.

High-level statements that toxin and energy delivery may not overlap, POR, 29-31, do not bridge this gap. The specification is silent about effects of energy in non-overlapping areas and does not describe *treatment* absent toxin. Instead it describes pairing a toxin delivery catheter *and* “energy applicator” to “enhance delivery *of the toxin*,” Ex.1001-USP011, 9:43-55, and treatment “enabled or enhanced” where toxin and energy *overlap*. *Id.*, 9:60-10:5; *see also id.*, 21:63-22:3. Ex.1098-Reply-Decl., ¶¶63-68.

Indeed, surrounding reference to “non-reversible poration,” the specification refers not to energy-only treatment, but states “the present invention” is “deliver[ing]” toxin “while applying energy,” and that energy “cause[s]...poration...*to enhance delivery of the toxin*....” Ex.1001-USP011, 8:6-13. In sentences immediately following the parenthetical (which PO omits), the specification describes “where *the toxin* is introduced,” a “target region for *the toxin*,” and cells “responsible for mucus secretion...susceptible to the disabling mechanism of the” *toxin*. *Id.*, 8:13-23. These passages do not describe the inventors possessed energy-only treatment/therapy. *Id.* Ex.1098-Reply-Decl., ¶¶63-68.

The Challenged Claims thus do not have written description and uncontested Grounds I-II render the claims unpatentable. Ex.1098-Reply-Decl., ¶¶48-69.

B. PO Cannot Rely on Nested Incorporation of the '771 Provisional

PO waived any argument it could legally claim priority before October 22, 2019 by not addressing the rule and cases in the Petition. Pet., 22-26; POR, 20-31; *Honeywell International, Inc. v. 3G Licensing S.A.*, IPR2021-01141, Paper 52, 9 (P.T.A.B. Jan. 11, 2023).

Regardless, Petitioners respectfully disagree with the Board's institution finding that 35 C.F.R. §1.57(d) does not apply to establishing written description for priority, and that PO could rely on nested incorporation of the '771 Provisional. ID, 16-17, n.4 (citing *Samsung Elecs. v. Acquis LLC*, IPR2021-00608, Paper 10 (P.T.A.B. Dec. 8, 2021)).

First, the Board's decision in *Samsung* that 35 C.F.R. §1.57(d) does not apply for establishing priority is incorrect. Section 1.57(d) states no such limitation, but that "essential material," including for "written description of the claimed invention" may not be incorporated by reference from a provisional. See 37 C.F.R. §1.57(d); *NRG Energy, Inc. v. Midwest Energy Emissions Corp.*, IPR2020-00832, Paper 17 (P.T.A.B. Oct. 26, 2020); *Focal Therapeutics, Inc. v. Senorx, Inc.*, IPR2014-00116,

Paper 8 (P.T.A.B. Apr. 22, 2014). Here, PO's priority claim using an incorporated provisional contravenes this Rule.⁷

Second, Applicant broke priority by dropping direct priority claims to and omitting content of the '771 Provisional from two applications preceding the October 22, 2019 application. Pet., 23-26; *Droplets, Inc. v. E*TRADE Bank*, 887 F.3d 1309, 1315-20 (Fed. Cir. 2018); *Hollmer v. Harari*, 681 F.3d 1351, 1355 (Fed. Cir. 2012); *Encyclopedia Britannica, Inc. v. Alpine Elecs. of Am., Inc.*, 609 F.3d 1345, 1351 (Fed. Cir. 2010); MPEP §211.02. The Board correctly noted these applications claim priority to the '090 application (which incorporates the '771 Provisional), ID, 15, but this nested incorporation is insufficient due to Applicant's affirmative break. *Lockwood*, 107 F.3d at 1571 (“**each** application” in chain “must comply with written description requirement”); Pet., 25-26.

⁷ *Ex parte Maziere*, 27 U.S.P.Q.2d 1705 (B.P.A.I. 1993) and M.P.E.P. §608.01(p) are inapplicable. *Maziere* was decided pre-§1.57 and addressed non-essential material. M.P.E.P. §608.01(p) (citing *Maziere*) is not binding and inconsistent with the Rule. *Nat. Alternatives Int'l, Inc. v. Iancu*, 904 F.3d 1375, 1382 (Fed. Cir. 2018) (citations omitted) (“MPEP ‘does not have the force of law[.]’”).

III. GROUND IV: CLAIMS 1-2, 5, 8-10, 12, AND 14 ARE OBVIOUS

If the Challenged Claims cannot claim earlier priority, Grounds I-II indisputably render the claims unpatentable. If Grounds I-II are not dispositive, Ground IV renders the Challenged Claims obvious at any priority date.

A. A POSITA Would Have Had a Reasonable Expectation Makower's Device (in view of Fang) Would Successfully Ablate Tissue

PO does not dispute Makower, Fang, and Edwards-535 teach all claim elements. Instead, PO argues that although Makower teaches its device ablates tissue to treat nasal disorders, Pet., 77-79, a POSITA would not expect it to do so. POR, 33-34. PO, however, identifies no teaching away, skepticism, or actual failure, and its technical mischaracterizations do not overcome reasonable expectation of success.

First, Makower is not limited to flexible catheters. POR, 34-35, 50-54. Makower's "present invention" includes "working devices" *separate from*

“catheters used to deliver them.” Ex.1005-Makower, [0161]-[0162]. Makower also *claims* working devices separately. *Id.*, claim 1.⁸ Ex.1098-Reply-Decl., ¶¶73-76.

Regardless, Makower’s inclusion of flexible catheters, and discussion of Figure 5H in several sentences, POR, 34-35, 50-54, are inconsequential. Makower indisputably teaches Figure 5H, Ex.1005-Makower, [0187], FIG.5H, and “must be considered for everything that it teaches[.]” *CRFD Research, Inc. v. Matal*, 876 F.3d 1330, 1349 (Fed. Cir. 2017) (citation omitted); *Sony Interactive Entertainment LLC v. Intellectual Pixals Ltd.*, 2023 WL 6773879, *4 (Fed. Cir. Oct. 13, 2023); *Neurent Medical Inc. v. Aerin Medical Inc.*, IPR2024-00278, Paper 9, 28-29 (PTAB, July 22, 2024) (rejecting same argument).

Second, a prior-art device need not be commercialized as PO argues (POR, 35, 42, 44), to support expectation of success. *Trustees of Columbia Univ. in City of New York v. Illumina, Inc.*, 620 F. App’x 916 (Fed. Cir. 2015) (“no requirement...the closest prior art be commercialized”); *Galderma Laboratories, L.P. v. Tolmar, Inc.*, 737 F.3d 731, 737 (Fed. Cir. 2013).

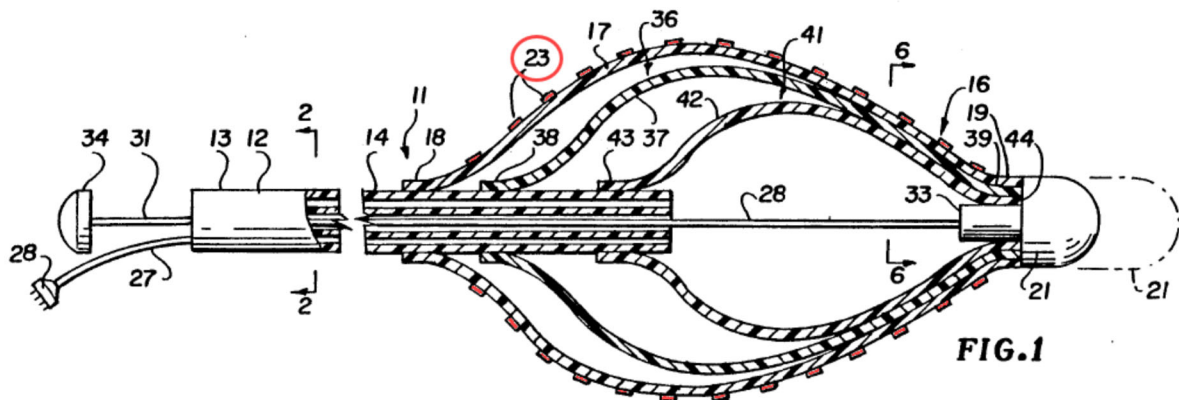
⁸ The ’011 patent confirms “flexible catheters” and radiofrequency devices are not mutually exclusive. Ex.1001-USP011, 16:21-26, 16:21-26; Ex.1089-Levine-Tr., 171:14-172:18.

Third, PO is incorrect that a POSITA would conclude—contrary to Makower’s teaching—that Figure 5H would not “properly deliver energy to target tissue to achieve the claimed therapeutic results.” POR, 33-43.⁹ PO argues Figure 5H is limited to ring electrodes and its hollow interior would purportedly fill with “electrolytic fluid” (mucus or blood), and not operate safely or effectively. POR, 35-42. Not so.¹⁰

Makower Figure 5H is not limited to ring electrodes. PO’s contrary assumption based on how it “appear[s],” POR, 35-38, ignores Makower does not recite “ring electrodes” but “electrodes 216” that are “bipolar, monopolar,” or use “other suitable” energy. Ex.1005-Makower, [0187]. Makower explains components of its device are well-known, and incorporates Imran, which teaches surface electrodes not facing the hollow interface.

⁹ Notably, Dr. Levine respects Dr. Makower’s engineering work “as high or beyond anyone that I know.” Ex.1089-Levine-Tr., 45:4-47:10.

¹⁰ PO does not contest Makower is presumed enabled for its teachings and bears the burden to show inoperability. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354-55 (Fed. Cir. 2003).



Ex.1068-Imran, FIG.1, 2:57-64, 3:2-7, claims 1, 62-66;¹¹ Ex.1005-Makower, [0164]. These teachings, not just Makower's "appearance," control. *Source Vagabond Sys. Ltd. v. Hydrapak, Inc.*, 753 F.3d 1291, 1300 (Fed. Cir. 2014). Contrary to PO's suggestion, a POSITA would have understood Makower teaches electrodes suitable for "causing tissue adjacent to the struts 214 to be...heated," Ex.1005-Makower, [0161]-[0161], [0187]; Ex.1089-Levine, 71:8-13, and not assume inoperable features. Ex.1098-Reply-Decl., ¶¶77-80.

Regardless, ring electrodes can ablate tissue, POR, 39-43, and such devices were well-known. Dr. Levine confirmed '011 patent Figure 5B uses a ring electrode, is covered by the claims, and is operable. Ex.1089, Levine-Tr, 195:4-196:6. A

¹¹ The Petition explains Figure 5H would be implemented using "well known" electrodes like Imran. Pet. 89; POR, 33 n.7. The two are connected, as Figure 5H is an electrode device. POR, 68. Ex.1098-Reply-Decl., ¶¶78-79.

POSITA implementing Makower Figure 5H using ring electrodes would have reasonably expected, as Makower teaches, they would successfully treat nasal tissue. Ex.1098-Reply-Decl., ¶¶89-91.

This treatment would not be impeded by electrolytic fluid, mucus, or blood, as PO suggests. POR 35-43. Dr. Levine confirmed mucus is present, but that during RF procedures “mucus isn’t the issue,” or alternatively, he would “suction it” or “irrigate the nose.” Ex.1089-Levine-Tr., 82:8-83:18. During RF procedures, Dr. Levine confirmed patients are positioned so that fluids “fall to the bottom” (i.e., away from the site) by “gravity.” *Id.*, 85:16-86:9. Dr. Bu-Saba agrees; in the nasal cavity/nasopharynx, Figure 5H would not fill with fluid, but with *air*, which insulates against current transmission. Ex.1091-Bikson-Tr., 218:9-11, 221:18-222:7; Ex.1001-USP011, 18:6-10 (describing air as insulator).¹² A POSITA would have understood Makower’s bipolar electrodes would deliver energy to treat

¹² Dr. Bikson’s opinions, Ex.2005-Bikson, ¶¶61-72, are undermined by his apparent belief RF ablation cannot be performed if *any* mucus/fluid is present. Ex.1091-Bikson-Tr, 218:2-8. Nasal RF ablation was routinely performed. Ex.1089-Levine-Tr, 48:10-14, 48:20-49:13, 49:14-50:12, 54:3-10; Ex.1098-Reply-Decl., ¶89.

contacted tissue, as Makower describes, with surface *or* ring electrodes. Ex.1005-Makower, [0187]. Ex.1098-Reply-Decl., ¶¶81-88.

Fourth, contrary to PO's argument, POR, 42-44, the Petition sufficiently addresses reasonable expectation of success. The Petition discusses Makower's device and its effects, including its teaching that Figure 5H will therapeutically apply energy to nasal cavity/nasopharynx tissue. Pet. 64-85. PO tellingly cites no law or reason Petitioners had to preemptively rebut PO's (faulty) inoperability argument. *Apple Inc. v. Andrea Elecs. Corp.*, 949 F.3d 697, 706 (Fed. Cir. 2020).¹³

Fifth, PO wrongly claims Fang's device was an "unknown quantity" and wrongly demands Makower and Fang's devices have been identical to support obviousness. POR, 43-46. Fang teaches device details relevant for reasonable expectation of success: Fang's device used RF electrodes to ablate tissue, like Makower's Figure 5H. Pet., 77-84; Ex.1006-Fang, 876. More details were not necessary for a POSITA to reasonably expect—consistent with multiple references—that Makower's electrodes would function similarly. Pet., 13-14, 83-

¹³ Dr. Bu-Saba considered Makower as a whole, *compare* POR, 42-43 *with* Ex.1002-Decl., ¶¶84, 150-208, and accurately explained certain (irrelevant) Figure 5H details are not specified/limited. Ex.1098-Reply-Decl., ¶¶92-94.

84; Ex.1002-Decl., ¶46 (citing references); Ex.1107-Levine-Article, 451; Section III.B.1. Ex.1098-Reply-Decl., ¶¶95-98.

Last, contrary to PO's argument, POR 45-46, Makower's device could be used in the locations Fang teaches. PO presumes (without citation) Makower's "rigid" "struts limit the tissue that can actually be treated." *Id.* Not so. Struts 214 "may be collapsible and expandible," for insertion into, e.g., the "nasal cavity." Ex.1005-Makower, [0187]. Figure 5H does not specify a particular location, Ex.2002-BuSaba-Tr., 285:20-286:6, it teaches its device can be used in multiple locations, e.g., "nasal cavity, meatus, ostium, interior of a sinus, etc." Ex.1005-Makower, [0187]. Makower, like the '011 patent, does not identify any challenges of applying energy throughout the nasal cavity. *Id.*; Ex.1001-USP011, 16:15-18:43; *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994) (lack of implementation detail in patent supports obviousness). Ex.1098-Reply-Decl., ¶¶99-101.^{14,15}

¹⁴ Makower teaches its device contacts tissue, Ex.1005-Makower, [0043], [0187], and in view of the specification, its drawing, POR, 46, does not convey otherwise. *Source*, 753 F.3d at 1300.

¹⁵ Fang's results are not "inconclusive." POR, 45; Section III.B.1.

A POSITA would have reasonably expected Makower's device to successfully treat rhinitis as Fang teaches. Ex.1098-Reply-Decl., ¶102.

B. A POSITA Would Have Been Motivated to Combine Makower and Fang

PO's arguments against motivation to combine Makower and Fang are legally irrelevant and unsupported. Each fails. Ex.1098-Reply-Decl., ¶103.¹⁶

1. A POSITA Would Have Considered Fang

PO's suggestion a POSITA would ignore or dismiss Fang's positive results—despite not contesting it is analogous art—POR, 47-50, should be rejected.

PO's argument rests on fundamental misapplication of law: Dr. Levine's opinion a POSITA would not consider Fang absent "conclusive proof." POR, 47-50; Ex.2003-Levine, ¶71. This is not required. *Acorda Therapeutics, Inc. v. Roxane Lab'ys, Inc.*, 903 F.3d 1310, 1333 (Fed. Cir. 2018) (no "requirement of '[c]onclusive

¹⁶ PO does not explain why the order of references is legally significant. POR, 46. It is not. *Schwendimann v. Neenah, Inc.*, 82 F.4th 1371, 1384 (Fed. Cir. 2023).

proof of efficacy””) (citations omitted); *In re Longi*, 759 F.2d 887, 896 (Fed. Cir. 1985) (“absolute predictability” unnecessary) (citations omitted).¹⁷

Fang’s teaching that nasal cavity/nasopharynx parasympathetic nerve ablation improved rhinitis outcomes was sufficient for motivation. Ex.1006-Fang, 876-877. Fang reports statistically significant improvements between a control (no ablation) and study group (with ablation), and teaches “**radiofrequency technique** completely blocks the parasympathetic pathway of the nasal mucosa,” which “reduces glandular secretion, and thus achieves the therapeutic purposes.” *Id.* That Fang’s authors performed additional procedures, POR, 47-48, does not diminish Fang’s attribution of rhinitis results to “radiofrequency,” as Fang’s other procedures treat other pathologies. Ex.1006-Fang, 876; Pet., 77-81. A POSITA would credit Fang’s results, not ignore them. Ex.1098-Reply-Decl., ¶¶104-106, 116-120.

PO tellingly does **not dispute** Fang was right about radiofrequency ablation and identifies no teaching away, skepticism, or failure. Fang’s findings are consistent with multiple undisputed prior-art references, *see* Ex.1002-Decl., ¶46

¹⁷ Dr. Levine was not instructed regarding reasonable expectation of success legal standards. Ex.1089-Levine-Tr., 160:5-18, 166:21-169:20; Ex.2003-Levine, ¶¶19-20.

(collecting references), **and** the '011 patent's admission blocking relevant cells with neurotoxin treated rhinitis symptoms was known. Ex.1001-USP011, 1:62-2:48, 3:27-51; Ex.1089-Levine-Tr, 199:12-15; *Incept LLC v. Palette Life Scis., Inc.*, 77 F.4th 1366, 1372 (Fed. Cir. 2023). Ex.1098-Reply-Decl., ¶¶107-108.

PO also wrongly faults Fang for not reciting sufficient study details and efficacy criteria. POR, 47-50. This is inconsistent with PO's priority argument that passing reference to non-reversible poration with **no** discussion of any study detail or outcome teaches treatment/therapy. *See* Section II; Ex.1089-Levine-Tr., 184:21-186:7, 172:9-173:17. But regardless, the claims require no particular level of efficacy, Ex.1001-USP011, claims, Ex.1089-Levine-Tr, 184:21-185:20, and clinical practice and studies have different standards. Ex.1089-Levine-Tr, 101:17-103:15. In any event, Fang cites efficacy criteria, Ex.1006-Fang, 877 n.1 (citing Ex.1113), that are consistent with criteria Dr. Levine used pre-2006. Ex.1089-Levine-Tr, 96:8-100:14. Ex.1098-Reply-Decl., ¶¶109-115.

Nor did Fang need to be peer reviewed or cited a certain number of times for motivation. POR, 49-50. A reference "must be viewed in the context of what was generally known" and for all it teaches. *In re Taylor Made Golf Co., Inc.*, 589 F. App'x 967, 971 (Fed. Cir. 2014) (citation omitted); *CRFD*, 876 F.3d at 1349. Fang was cited at least seven times, Ex.1103 (not once, POR, 50), and Hytönen (which

PO referenced but did not submit, Ex.2008), cited Fang's results positively and as motivating further study. Ex.1112-Hytönen, 1261, 1264.¹⁸ Ex.1098-Reply-Decl., ¶¶120-123.

2. A POSITA Would Have Considered Makower

As Section III.A discusses, Makower is not limited to flexible catheters, POR 50-54; it specifically teaches and claims "working devices." Ex.1098-Reply-Decl., ¶¶124-125.

3. A POSITA Would Have Been Motivated to Combine Makower and Fang

PO's arguments against motivation to use Makower's ablation device to achieve Fang's results, POR, 55-65, fail.

First, Petitioners did not use hindsight. POR 55-64. PO does not contest Makower is analogous art. *Id.*, 64. A POSITA considering nasal disorder treatments would look to Makower's devices, Ex.1005-Makower, [0001], [0132]; Pet., 77-79, which the Examiner independently confirmed during family prosecution. Ex.1022-

¹⁸ PO also cited Fang during prosecution of U.S. Appl. No. 18/177,875. Makower has been cited over 700 times. Ex.1115.

FH675, 122 (Makower “closest prior art”).¹⁹ As Section III.A discusses, whether Figure 5H was “proven” or widely known, POR, 56, is irrelevant. *See Netflix, Inc. v. DivX, LLC*, 80 F.4th 1352, 1358 (Fed. Cir. 2023). Ex.1098-Reply-Decl., ¶¶126-130.

Second, Makower’s device is not limited to removing obstructions. POR, 56-57, 59-62.²⁰ “Tissue shrinking” is, in Figure 5H, achieved through ablation. As Makower explains, “further aspects [and] details” of its devices were “understood” by POSITAs, Ex.1005-Makower, [0046], and one motivated to perform “therapeutic procedures” in the “nasal cavity” or “nasopharynx” would have looked to Fang to explain further effects of ablation. Pet., 77-81; Ex.1098-Reply-Decl., ¶¶131-135.

¹⁹ Petitioners’ citation to this history was proper. POR, 62-64. *Google LLC v. Valtrus Innovations Ltd.*, IPR2022-01406, Paper 40, 69-70 (P.T.A.B. Apr. 3, 2024) (“prosecution history” supported obviousness)

²⁰ Obstruction and rhinitis treatment are also not mutually exclusive; rhinitis symptoms include obstruction (Ex.1089-Levine-Tr, 101:1-8, 101:17-102:10) and Dr. Levine’s lasers treated both (Ex.1107-Levine-Article, 453). *See also* Ex.1107, 453 (mucus secretion reduction incident to turbinate reduction).

Third, as Section III.A discusses, PO has not shown that Makower Figure 5H is inoperable. POR, 56; Ex.1098-Reply-Decl., ¶135.

Fourth, Makower and Fang do not have “diametrically opposed objectives and treatment effects” or “fundamental differences.” POR, 56-58. Both disclose treating nasal conditions by applying energy to tissue. Ex.1006-Fang, 876-877; Ex.1005-Makower, [0001], [0043], [0132], [0164], [0187]. Makower describes problems with *undesired* trauma from rigid instrumentation. *E.g.*, Ex.1005-Makower, [0161]. Fang’s non-ablative resection techniques, however, are *medically desirable* for addressing conditions other than rhinitis. Ex.1006-Fang, 876-77; *see* Ex.1089-Levine-Tr, 89:12-91:8, 91:19-92:7. Far from opposing or teaching away from such procedures, Makower discusses performing them. *See, e.g.*, Ex.1005-Makower, [0043] (e.g., cutting, debulking, remodeling, scraping, and removing). As Dr. Levine admitted, it is “not unusual to combine several procedures.” Ex.1089-Levine-Tr, 89:12-91:8. Ex.1098-Reply-Decl., ¶¶136-138.

Fifth, a POSITA would not have to use Figure 5H for undesirable ablation. POR, 58-61. A POSITA would adjust the device’s position and/or radiofrequency parameters, e.g., by selectively activating electrodes contacting target nasal-wall tissue. Ex.1005-Makower, [0043], [0161], [0164], [0187]. And Dr. Levine has

ablated the septum, Ex.1089-Levine-Tr, 49:14-50:12, contradicting PO's suggestion that would be improper. Ex.1098-Reply-Decl., ¶¶139-143.

Last, obviousness of Makower Figure 5A, POR, 61-62, does not defeat obviousness of Figure 5H. *See Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 800 (Fed. Cir. 2021) (unnecessary to show suitable combination best option).

Accordingly, a POSITA would have been motivated to apply Fang's method with Makower's device to treat rhinitis symptoms. Ex.1098-Reply-Decl., ¶144.

C. Claim 9: Makower Teaches Concentrating Energy Laterally

PO's arguments regarding the direction Makower concentrates energy, POR, 65-70, are wrong. Makower Figure 5H concentrates energy laterally relative to the distal portion of the treatment device (i.e., in tissue) when current travels between bipolar electrodes, Pet., 89-90, just like the direction energy is concentrated in '011 patent Figure 5A.²¹ Ex.1098-Reply-Decl., ¶¶145-146.

PO raises different arguments regarding ring electrodes and Imran's surface electrodes. POR, 65-70. If Makower required ring electrodes (it does not), they would concentrate energy *at least* laterally, i.e., away from the distal portion of the

²¹ The POR does not address PO's infringement allegations, which undermine PO's position. Pet., 90.

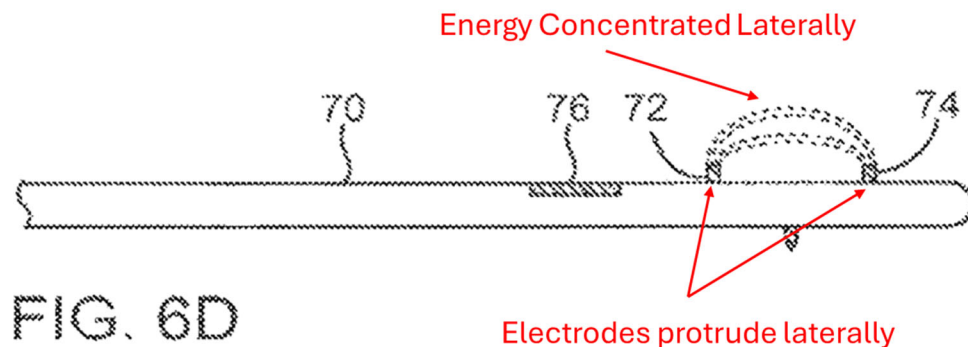
treatment device and into tissue. Ex.1089-Levine-Tr. 194:5-7 (Fig. 5B ring electrode delivers energy uniformly *and* laterally), 195:4-196:6. They would not require additional “insulation” as PO argues. POR, 66. As an initial matter, claim 9 does not recite or require insulation.²² But regardless, a POSITA would have expected ring electrodes in Makower would concentrate energy laterally because air would insulate any portion not contacting tissue. Ex.1091-Bikson-Tr., 218:9-11, 221:18-222:7; Ex.1001-USP011, 18:6-10; 23:60-65. Ex.1098-Reply-Decl., ¶¶147-148, 151-152.

If Figure 5H were implemented with Imran’s surface bipolar electrodes,²³ it would do the same. Ex.1005-Makower, [0164]; Ex.1068-Imran, FIG.1, claim 1, 62-

²² Petitioners cited Figure 5A of the ’011 patent as an example of the lateral direction of the energy field and did not argue or concede the *only* arrangement of electrodes that could deliver energy laterally was in that Figure or that “lateral energy requires a specific electrode configuration.” Pet., 89-90; POR, 67. The ’011 patent does not limit its claims in that way.

²³ PO’s allegations of hindsight because Imran is one of twenty incorporated patents, POR, 68, are misplaced, as Figure 5H is a Makower embodiment with electrodes.

66, 2:57-64, 3:2-7; Pet., 89-90. Imran teaches extending surface bipolar electrodes that would concentrate energy like '011 patent Figure 6D, which confirms laterally protruding bipolar electrodes would pair to create energy fields concentrated laterally from the device (into tissue).²⁴



Ex.1001-USP011, FIG.6D. Ex.1098-Reply-Decl., ¶¶149-150.

Contrary to PO's suggestion, POR, 68, the Petition does address Imran. Pet., 89; Ex.1002-Decl., ¶202. Ex.1098-Reply-Decl., ¶149.

²⁴ Undermining its analysis, PO's response in IPR2024-00279 argues (inconsistently, and wrongly) that Imran's electrodes would actually function like ring electrodes and not that energy would be delivered through multiple surfaces. IPR2024-00279, POR (Paper 22), 63-66. It is unclear which of these inconsistent positions about the same reference PO prefers, but in any event, both theories are inconsistent with the '011 patent.

In this way, PO's arguments Imran's protruding electrodes would not deliver energy laterally (Ex.2003-Levine, ¶109; Ex.2005-Bikson, ¶82; Ex.1089-Levine-Tr., 187:7-188:5), are directly contradicted by the '011 patent, which in Figure 6D depicts electrodes that "extend laterally" *and* create a lateral "energy field" akin to Figure 5A, and in claim 10 claims energy transmission elements that *both* extend *and* deliver energy laterally. Ex.1001-USP011, FIG.6D, 17:27-35, claims 1, 9-10; *see* Ex.1089-Levine-Tr, 190:6-9 (patent's energy fields accurate). Ex.1098-Reply-Decl., ¶153.

Accordingly, Makower teaches claim 9.

IV. PO's POSITA Disputes Are Irrelevant But Wrong

PO's POSITA-definition dispute (POR, 18-20) does not affect a specific contested issue but is solely a tactic to wrongly disparage Petitioners' expert. The Board should reject this gambit.²⁵

A POSITA indisputably had an M.D. or engineering degree and three years' experience. Pet., 18-19; POR, 18-20. PO argues design or development (not clinical use or testing) experience is required; and nasal (not general) medical device

²⁵ PO waived any argument the POSITA definition affects written description/priority.

experience is required. POR, 18-20.²⁶ Each is irrelevant and wrong. Ex.1098-Reply-Decl., ¶¶12-17.

A. Dr. Bu-Saba is a POSITA For All Contested Issues

Dr. Bu-Saba's testimony is supported by his extensive clinical expertise. PO only raises a specific skill level issue regarding operation of Makower Figure 5H. POR, 19, n.4, 35-46. PO's (incorrect) argument, however, turns on anatomy and clinical implementation (presence of mucus/blood), not device design or development.²⁷ Dr. Bu-Saba—a Board-certified otolaryngologist with extensive RF device experience—had the skill to explain PO inaccurately describes where mucus is.²⁸ Dr. Levine agrees Dr. Bu-Saba is a nasal cavity/nasopharynx anatomy expert, Ex.1089-Levine-Tr., 170:21-171:2, and Dr. Levine also advises Aerin on adverse event responses as a *clinician*. *Id.*, 18:14-22, 19:15-20:3. Dr. Bu-Saba's experience

²⁶ Dr. Levine's different definition, Ex.2003-Levine, ¶38, is incorrect for the same reasons.

²⁷ Tellingly, though Dr. Levine has *no* electrode design/development experience (and consulted Dr. Bikson), PO offers his testimony regarding bipolar electrode operability. Ex.1089-Levine-Tr., 157:12-159:5, 192:2-13.

²⁸ Disparagement aside, PO and Dr. Levine extensively cite Dr. Bu-Saba.

supports his opinions and PO's manufactured dispute is irrelevant. *Incyte Corp. v. Concert Pharms., Inc.*, PGR2021-00006, Paper 68, 8-9 (P.T.A.B. May 11, 2022) (crediting expert opinions within areas of expertise). Ex.1098-Reply-Decl., ¶21.²⁹

Regardless, PO's POSITA definition is wrong³⁰:

- The Challenged Claims' purported solution relates to delivering energy with generic (not specialized) components. Ex.1001-USP011, claim 1.
- Clinicians used RF devices safely and effectively in the nose, including using "factory settings." Ex.1001-USP011, 16:37-53, 16:37-53, 18:20-33, 19:22-29;

²⁹ The Board can, however, consider Dr. Levine's bias. Dr. Levine is *currently* consulting for (and received over \$45,000 from) RPI Aerin and has significant relationships with Aerin principals. Ex.1089-Levine-Tr., 18:1-35:21, 36:11-44:22, 151:10-156:21; Ex.1090. Though PO critiques Dr. Bu-Saba for not previously testifying in patent cases, POR, 19, n.4, the Board rejected Dr. Levine's positions in his two cases. Ex.1105, Ex.1106.

³⁰ POSITA factors (which PO did not apply) include prior-art problems and solutions, rapidity of innovation, technology sophistication, and educational level in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 1201 (Fed. Cir.1986).

Ex.1006-Fang, 876-77. Dr. Levine performed nasal RF ablation in the 1990s without electrode design or development experience. Ex.1089-Levine-Tr., 54:3-10, 157:12-159:5.

- Clinicians learned safe and effective RF device operation through use, testing, instructions, education, and data. Ex.1089-Levine-Tr., 62:7-63:11, 74:9-75:11.
- Devices were unsophisticated: artisans chose between device types, selected settings and dosage, provided feedback, and used devices off-label “based on...experience as a clinician.” Ex.1089-Levine-Tr., 13:10-16, 72:16-75:11, 122:19-124:3.
- Physicians “*must* be familiar” with devices’, e.g., “safety, energy dosage...and instrumentation.” Ex.1107-Levine-Article, 451; Ex.1091-Bikson-Tr, 89:2-94:8. “Clinician[s]” need not have developed a device to “see another place it could be used.” Ex.1089-Levine-Tr, 124:19-125:13.

Thus, ordinary skill included an M.D. or engineer with three years’ use and/or testing experience. Excluding clinical use/testing from claims involving treatment/therapy is illogical. Ex.1098-Reply-Decl., ¶¶18-34.

B. A POSITA Did Not Require Nasal Medical Device Experience

PO also argues that a POSITA had “nasal medical device” experience, and not just “medical device” experience. POR, 19. PO’s argument undermines its own

declarant Dr. Bikson, who has *no* nasal medical device experience. *See* Ex.2005-Bikson, ¶¶36-42; Ex.1091-Bikson-Tr, 63:17-64:9, 80:4-81:1, 25:10-26:13. Regardless, this dispute is irrelevant. Petitioners' declarant Dr. Bu-Saba, indisputably has nasal medical device experience. Dr. Bikson also testified his opinions would not change under either party's POSITA definition. Ex.2005-Bikson, ¶39.

Regardless, PO's definition is also wrong:

- The '011 patent discusses “delivering neurotoxins” in “*any*...target region,” not just the nose, and identifies no purportedly challenging nasal anatomy. Ex.1001-USP011, 2:19-63, 4:65-5:12, 4:61-65, 8:6-31, 17:7-11, 20:17-25, 21:11-32, claim 1.³¹
- Prior-art problems and solutions were addressed with generic RF devices with “factory settings” (*e.g.*, Ex.1006-Fang, 876-77), and devices usable in multiple locations (*e.g.*, Ex.1005-Makower, [0043] (ear, nose, throat); Ex.1009-Stern, 1:15-23). Stern (uterine ablation) is indisputably analogous art. Dr. Levine

³¹ Dr. Bu-Saba did not testify POSITAs need nasopharynx experience, POR, 19, but that nasopharynx-specific questions would be directed to someone with knowledge. Ex-2002-Bu-Saba-Tr., 125:15-127:11.

admitted his prior-art laser device was informed by safety experience in other body areas. Ex.1089-Levine-Tr, 126:3-9; Ex.1107-Levine-Article, 451.

- PO represented multiple non-nasal references were material during prosecution. Ex.1022-USP675FH, 133-149 (citing Ex.1110, Ex.1111).
- The named inventors are engineers, and PO offers no evidence either had prior nasal experience. *See* Ex.1108-Deem; Ex.1109-Gifford. The '011 patent cites *others'* nasal anatomy work. Ex.1001-USP011, 3:27-51.
- Generic device elements claimed are not sophisticated, contingent, or site-dependent. The '011 patent recites few implementation and no performance details.
- Dr. Levine confirmed biomedical engineers “take in information from clinicians” to create devices. Ex.1089-Levine-Tr., 202:6-203:2. Engineers had extensive literature regarding nasal anatomy/pathology available. *See* Pet., 8-15.

Thus, the POSITA factors support ordinary skill included three years' medical device experience. Nasal anatomy and physiology “complex[ity]” POR, 18, is inconsequential. The '011 patent does not turn on such complexities; it addresses *any* “target cells.” Ex.1001-USP011, 4:27-50, 4:61-65. Under Petitioner's definition a POSITA would have the skill—with relevant literature and/or clinician consultation—to apply general principles to a nasal device. *See Hologic, Inc. v.*

Minerva Surgical, Inc., 764 Fed. Appx. 873, 879 (Fed. Cir. 2019) (non-precedential) (affirming finding POSITA had general (not uterine-ablation-specific) electrosurgical device experience where patent applied to multiple body cavities); *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010) (allowing testimony from engineer with polymer experience without air-fryer-specific experience); *Medtronic, Inc. v. Teleflex Life Sciences Limited*, IPR2020-01343, Paper 85, 17-18 (P.T.A.B. Feb. 23, 2022). Ex.1098-Reply-Decl., ¶¶35-46.³²

To the extent necessary, the Board should adopt Petitioners' POSITA definition.

V. CONCLUSION

The Challenged Claims are unpatentable and should be canceled.

³² Aerin argues POSITAs had general (non-nasal-specific) device experience in similar IPRs. *Neurent Medical Inc. v. Aerin Medical Inc.*, IPR2024-00277, Paper 24, 8. Drs. Levine and Bikson elsewhere concluded clinician POSITAs need not have designed or developed devices and engineer POSITAs need not have particular anatomy experience. Ex.1104, ¶¶17-23, Ex.1116, ¶23.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing, Petitioners' Reply, contains 5,357 words as measured by the word processing software used to prepare the document, in compliance with 37 C.F.R. §42.24(d), excluding the parts of the Petition exempted from the word count by 37 C.F.R. §42.24(a)(1).

/Gilbert Smolenski/
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CERTIFICATE OF SERVICE

I hereby certify that, on January 17, 2025, I caused a true and correct copy of the following materials:

- Petitioners' Reply
- Petitioners' Table of Exhibits
- Exhibits 1089-1098, 1101, 1103-1116
- Certificate of Compliance Regarding Word Count

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Petitioners' Table of Exhibits

No.	Description
1001.	U.S. Patent No. 10,894,011
1002.	Declaration of Dr. Nicolas Bu-Saba
1003.	U.S. Patent No 10,307,200 to Saadat
1004.	U.S. Patent Pub. No. 2008/0021369 to Deem
1005.	U.S. Patent Pub. No. 2005/0240147 to Makower
1006.	Fang (Translation)
1007.	Reserved
1008.	U.S. Patent No. 6,517,535 to Edwards
1009.	U.S. Patent No. 5,562,720 to Stern
1010.	U.S. Provisional Appl. No. 60/702,077
1011.	U.S. Provisional Appl. No. 60/747,771
1012.	U.S. Patent No. 7,608,275
1013.	U.S. Patent No. 8,133,497
1014.	U.S. Patent No. 8,338,164
1015.	U.S. Patent No. 8,961,391
1016.	U.S. Patent No. 9,498,283
1017.	U.S. Patent No. 10,022,529
1018.	Prosecution history for U.S. Patent No. 10,022,529
1019.	U.S. Patent No. 10,729,897
1020.	Prosecution history for U.S. Patent No. 10,729,897
1021.	U.S. Patent No. 10,610,675
1022.	Prosecution History for U.S. Patent No. 10,610,675
1023.	Reserved
1024.	Prosecution History for U.S. Patent No. 10,894,011
1025.	Reserved
1026.	U.S. Patent No. 7,655,243
1027.	Prosecution History for U.S. Patent No. 7,655,243
1028.	Prosecution History for U.S. Patent No. 8,636,684
1029.	U.S. Patent No. 8,105,817
1030.	U.S. Patent No. 8,636,684
1031.	U.S. Patent Pub. No. 2014/0114233
1032.	U.S. Patent No. 9,700,707
1033.	U.S. Patent No. 10,052,465
1034.	File History for U.S. Patent No. 10,335,221 assigned to Aerin

No.	Description
1035.	<i>Aerin Medical Inc. v. Neurent Medical Inc.</i> , 1:23-cv-00756-GBW, Amended Complaint for Patent Infringement, Dkt. 17 (October 16, 2023) (“Amended Complaint”)
1036.	Reserved
1037.	Exhibit W to Amended Complaint – Foundry’s Infringement Allegations for U.S. Patent No. 10,894,011
1038.	Reserved
1039.	Docket Navigator District of Delaware Statistics as of January 18, 2024
1040.	U.S. Patent No. 8,939,970 to Stone
1041.	Stedman’s Medical Dictionary (27th ed. 2001)
1042.	PDR Medical Dictionary (2nd ed. 2000)
1043.	Kong Yonggang, <i>Low-temperature plasma ablation of inferior turbinate for the treatment of perennial allergic rhinitis</i> , 19(5) J Clin. Otorhinolaryngol 214 (Mar. 2005) (Translation) (“Kong”)
1044.	Chen Shi-qiang et al., <i>Preliminary study on radiofrequency thermocoagulation of the posterior inferior nerve, anterior ethmoidal nerve, and inferior turbinate under nasal endoscopy for the treatment of perennial allergic rhinitis</i> , 11(3) China Journal of Endoscopy 239 (Mar. 2005) (Translation) (“Chen”)
1045.	Liang Jianping, <i>Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy</i> , 13(8) J Clin. Otorhinolaryngol 341 (Aug. 1999) (Translation) (“Liang”)
1046.	U.S. Patent No. 6,669,689 to Lehmann
1047.	U.S. Patent No. 6,685,648 to Flaherty
1048.	Stedman’s Medical Dictionary (26th ed. 1995)
1049.	Webster’s Third New International Dictionary (2002)
1050.	Seth Waxman, <i>Correlative Neuroanatomy</i> (23rd ed. 1996)
1051.	Robert E. Windsor and Scott Jahnke, <i>Sphenopalatine Ganglion Blockage: A Review and Proposed Modification of the Transnasal Technique</i> , Pain Physician 7:283-286 (2004)
1052.	Ralph Fenton, <i>Current Evaluation of Nasopharyngeal Defense Mechanisms</i> (1955)
1053.	U.S. Patent No. 6,517,534 to McGovern

No.	Description
1054.	M.M. L. Arora, <i>Cryodestruction of Vidian Nerve Branches</i> , 32:3 Indian J. Otolaryngology 80 (Sept. 1980)
1055.	U.S. Patent Pub. No. 2014/0243793 to Morriss
1056.	Maureen Sackenheim, Radio Frequency Ablation, JDMS 19:88-92 (March/April 2003)
1057.	U.S. Patent No. 5,766,605 to Sanders
1058.	U.S. Patent No. 874,178 to De Forest
1059.	U.S. Patent Pub. No. 2005/0171574 to Rubinsky
1060.	U.S. Patent No. 3,538,919 to Meyer
1061.	U.S. Patent No. 3,117,571 to Fry
1062.	International Pub. No. 2016/183337 to Townley
1063.	Reserved
1064.	Andrew Lane, <i>Nasal anatomy and physiology</i> , Facial Plast. Surg. Clin. N. Am. 12:387-395 (2004)
1065.	Gray's Anatomy (2003)
1066.	U.S. Patent No. 6,273,886 to Edwards
1067.	Reserved
1068.	U.S. Patent No. 5,255,679 to Imran
1069.	Reserved
1070.	Declaration of June Munford
1071.	Translator Declarations for Chen
1072.	Translator Declarations for Liang
1073.	Translator Declarations for Fang
1074.	Translator Declarations for Kong
1075.	Munford Appendices for Chen
1076.	Munford Appendices for Liang
1077.	Munford Appendices for Fang
1078.	Munford Appendices for Kong
1079.	Munford Appendices for Shanghai
1080.	Reserved
1081.	Reserved
1082.	Reserved
1083.	Reserved
1084.	Reserved
1085.	Reserved
1086.	Reserved

No.	Description
1087.	Declaration of Gregory H. Lantier
1088.	Declaration of Joshua L. Stern
1089.	Deposition Transcript of Dr. Howard Levine
1090.	Levine Deposition Exhibit 1
1091.	Deposition Transcript of Dr. Marom Bikson
1092.	Bikson Deposition Exhibit A
1093.	Bikson Deposition Exhibit B
1094.	Bikson Deposition Exhibit C
1095.	Bikson Deposition Exhibit D
1096.	Bikson Deposition Exhibit E
1097.	Bikson Deposition Exhibit F
1098.	Reply Declaration of Dr. Nicolas Bu-Saba
1099.	Reserved
1100.	Errata from the October 17, 2024 Deposition of Dr. Nicolas Bu-Saba
1101.	Reserved
1102.	Reserved
1103.	Google Citations for Fang (Ex.1005)
1104.	Excerpts from the Declaration of Dr. Howard Levine filed in IPR2017-00498
1105.	Final Written Decision in IPR2017-00498
1106.	Institution Decision in IPR2018-00268
1107.	Howard L. Levine, Lasers in Endonasal Surgery, Otolaryngologic Clinics of N. Am. 30:3, 451-455 (June 1997)
1108.	Pitchbook Profile of Mark Deem
1109.	Resume of Hanson Gifford
1110.	U.S. Patent No. 6,658,279
1111.	U.S. Patent No. 7,628,789
1112.	Hytönen et al., Radiofrequency Thermal Ablation for Patients with Nasal Symptoms: A Systematic Review of Effectiveness and Complications, 266 EUR. ARCH. OTORHINOLARYNGOL. (2009) (“Hytönen”)
1113.	Haikou, Diagnostic Criteria and Efficacy Evaluation Criteria of Allergic Rhinitis, 33:3 Chin. J. Otorhinolaryngol 134 (June 1998)

No.	Description
1114.	Translation Declaration for Haikou
1115.	Derwent Innovation Record for Makower (Ex.1005)
1116.	Excerpts from the Declaration of Dr. Marom Bikson filed in IPR2022-00511